## REMARKS

Please reconsider the application in view of the above amendments and the following remarks. Applicant thanks the Examiner for carefully considering this application.

# **Preliminary Matter**

Please change the attorney docket number to: 17469/004001.

## **Disposition of Claims**

Claims 1-9 are pending in this application. Claims 1 and 5-7 are independent claims. The remaining claims depend, directly or indirectly, from claim 1.

#### Claim Amendments

Claims 1-2 and 5-7 have been amended to clarify the invention recited. Support for these amendments can be found in Examples 1-8. No new matter is introduced.

### Rejection(s) under 35 U.S.C. § 112

Claims 1-9 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the inclusion of "main components ..." The claims have been amended to remove these phrases. Accordingly, withdrawal of this rejection is respectfully requested.

## Rejection(s) under 35 U.S.C. §103(a)

Claims 1-9 were rejected under 35 U.S.C. §103(a) as being unpatentable over Murad (U.S. Patent No. 6,630,163), in view of Murad (U.S. Patent No. 5,962,517), and further in view of Gildenburg et al. (U.S. Patent No. 6,217,852). Claims 1-2 and 5-7 have been amended. To the extent that this rejection may still apply to the amended claims, this rejection is respectfully traversed.

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As discussed in the present specification, prior art compositions often include vitamin A or its derivatives (e.g., Vitamin A acid). Vitamin A derivatives, especially vitamin A acid, may make the skin sensitive to light and may lead to dry skin, red swelling, itching and dermatitis. (see paragraph [0012] in U.S. 2004/0228908).

Embodiments of the invention use <u>carotene</u> instead of vitamin A (or its derivatives). Vitamin A typically refers to retinol or retinal. Vitamin A (especially the aldehyde form) can be readily oxidized to retinoic acid (vitamin A acid). Various vitamin A derivatives (alcohol, aldehyde, acid, and ester) belong to the "retinoid" family. Although carotene can be converted into vitamin A via multiple enzymatic steps <u>inside</u> our body, carotene belongs to the "carotenoid" family, not the retinoid family, and is a chemical distinct from any of the retinoid family members. (see the following structures). Therefore, a <u>topical</u> composition comprising carotene is distinctly different from that containing vitamin A, and vice versa.

The examiner asserts that if a composition contains carotene, this composition is not substantially free of vitamin A or its derivatives, because carotene is a precursor of vitamin A. (Office Action, p. 8). The patentability of a composition should be judged based on its components as claimed, not how it could have been converted inside our body. Furthermore,

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these are topical compositions to be used on the skins. They will not encounter the necessary enzymes to convert carotene into vitamin A.

That one skilled in the art would not consider that a vitamin A derivative includes carotene is evident in the Murad '517 patent cited by the examiner. The acne reducing composition disclosed in Murad '517 patent includes a vitamin A source and a carotenoid component, among other things. If vitamin A source includes carotenoids, then they will not be listed separately.

In any event, to expedite the prosecution of the present invention, Applicant has amended the claims to specifically recite retinol, retinal, and retinoic acid, instead of vitamin A and vitamin A acid in order to avoid any confusion. Specifically, the amended claims include the limitation, "wherein the composition is substantially free of retinol, retinal, retinoic acid, and an ester of retinol or retinoic acid." Note that this limitation is based on inventors' finding that vitamin A acid can produce undesirable side effects as discussed in paragraph [0012] of the published application 2004/0228908. Therefore, a composition of the invention uses carotene (which will not be converted into vitamin A on skin) instead of any vitamin A derivative.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's

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disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). MPEP § 2142. (emphasis added).

Applicant respectfully submits that a combination of Murad '517, Murad '163, and Gildenburg '852 fails to teach or suggest all limitations of the amended claims 1 and 5-7. Specifically, they fail to teach or suggest at least one limitation of the claims of the invention, i.e., "wherein the composition is substantially free of retinol, retinal, retinoic acid, and an ester of retinol or retinoic acid."

Murad '517 teaches a pharmaceutical composition for the treatment of acne comprising an acne reduction component. The acne reduction component is a vitamin A source, a carotenoid component, a vitamin B<sub>6</sub> source, and a zinc component. (Col. 3, lines 41-43; 56-58). This composition is similar to the compositions of the present invention. However, it includes a vitamin A source. Specifically, Murad '517 teaches "Vitamin A is necessary for healthy skin cell growth and tissue formation." (Col. 5, lines 60-61).

Murad '163 teaches a dermatological agent including at least one fruit extract from pomegranate. (Col. 6, lines 26-28). The composition may further comprise a moisturizing agent, a sunscreen or sunblock component, antioxidants, etc. The antioxidants may be a catechin-based preparation, a vitamin A source, a ginko biloba extract, a silymarin source, a quercetin compound, a vitamin C source, a carotenoid, or a mixture thereof. (Col. 7, lines 8-11). The vitamin A is typically present in an amount from about 5 to 50 weight percent. (Col. 14, lines 57-59).

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Gildenburg teaches personal cleansing compositions having photoprotective agents. Specifically, Gildenburg et al. taught a composition for use as a sunscreen applied during washing. The composition includes photoprotective agents of the organic type (e.g., octylmethyoxy cinnamate and oxybenzone), the inorganic type (e.g., titanium oxide and zinc oxide), or combinations of the organic and inorganic agents. (Abstract) Examiner cites Gildenburg for the teaching of surfactants.

Although obviousness can be established by combining or modifying the teachings of the prior art to produce the claimed invention, none of the cited references provide teaching, suggestion, or motivation to do so. Specifically, none of these references recognize the drawback of having vitamin A or vitamin A acid in a topical composition. Therefore, none of these references teach or suggest "wherein the composition is substantially free of retinol, retinal, retinoic acid, and an ester of retinol or retinoic acid."

In view of the above, a combination of Murad (U.S. Patent No. 6,630,163), Murad (U.S. Patent No. 5,962,517), and Gildenburg et al. (U.S. Patent No. 6,217,852) fail to teach or suggest each and every limitation of the independent claims 1 and 5-7. Therefore, claims 1 and 5-7 are patentable over these references. Dependent claims should also be patentable for at least the same reasons. Accordingly, withdrawal of this rejection is respectfully requested.

## Conclusion

Applicant believes this reply is fully responsive to all outstanding issues and places this application in condition for allowance. If this belief is incorrect, or other issues arise, the Examiner is encouraged to contact the undersigned or his associates at the telephone number listed below. Please apply any charges not covered, or any credits, to Deposit Account 50-0591 (Reference Number 10112/004001).

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Respectfully submitted,

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